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Re-evaluation Note

REV2014-07

Special Review of Quintozene: Proposed Decision for Consultation

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1.0 Introduction

Pursuant to subsection 17(2) of the *Pest Control Products Act*, the Pest Management Regulatory Agency (PMRA) has initiated a special review of pest control products containing quintozone based on decisions taken by the European Commission in 2000 and by Switzerland in 1998. The initiation of the special review under the *Pest Control Products Act* was announced in December 2013.¹

Pursuant to subsection 18(4) of the *Pest Control Products Act*, the PMRA has evaluated the aspects of concern that prompted the special review. The aspects of concern are occupational and dietary exposure, persistence in the environment, bioaccumulation, effects on earthworms and toxicity to aquatic organisms.

2.0 Uses of Quintozone in Canada

Quintozone is a fungicide first registered in Canada in 1951. The PMRA completed the re-evaluation of quintozone in 2009.^{2,3} Following re-evaluation, most uses of quintozone were cancelled with the exception of uses on ornamentals (bulb dip) and cole crops which were deemed acceptable for continued registration with risk mitigation measures. Subsequently, all end use products containing quintozone have been discontinued in Canada and cannot be used after 26 April 2015. There are two technical grade active ingredient products registered in Canada. The proposed special review decision is applicable for all registered products containing quintozone (Appendix I).

3.0 Aspects of the Pest Control Product that Prompted the Special Review

European Commission

The use of quintozone in European Union (EU) Member States was prohibited in 2000 due to human health and environmental concerns.⁴ The European Commission Review Report⁵ in support of the decision indicates that the “information available is insufficient to satisfy the requirements set out in Annex II and Annex III Directive 91/414/EEC in particular with regard to the environmental fate and ecotoxicology of the substance and its main metabolite and with regard to certain data gaps concerning mammalian toxicology and residues.” The European Commission review report indicates that “based on the information available and the proposed conditions of use it was concluded that a risk of non-target organisms exposed to quintozone cannot be excluded and that there are concerns on the persistence of the active substance and on the safety of operators and consumers.” In addition, the review report indicated that “the main

¹ Canada, 2013, Pest Management Regulatory Agency Regulatory Note REV2013-06, *Special Review Initiation of 23 Active Ingredients*.

² Canada, 2009, Pest Management Regulatory Agency. Proposed Re-evaluation Decision PRVD2009-02, *Quintozone*.

³ Canada, 2010, Pest Management Regulatory Agency. Re-evaluation Decision RVD2010-06, *Quintozone*.

⁴ European Commission, 2000a. Commission Decision concerning the non-inclusion of quintozone in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant-protection products containing this active substance. (2000/816/EC).

⁵ European Commission, 2000b. Review report for the active substance quintozone.

notifier of the substance, formally withdrew its support for quintozone within the EU Peer Review Programme and, therefore, no engagements are made to produce the necessary supplementary data.”

The European Commission Review Report cites concerns for persistence and the safety of operators and consumers (occupational and dietary exposure); consequently, the PMRA identified these as aspects of concern. The European review report indicates that based on the available information and the proposed conditions of use, a risk to non-target organisms cannot be excluded; however, no specific risk concerns to non-target species were identified.

Switzerland

All uses of quintozone were prohibited for use in Switzerland in 1998. The 2004 Rotterdam Convention Prior Informed Consent (PIC) Circular⁶ indicates that reasons for the final regulatory action were related to the environment and cites effects on earthworms, toxicity to aquatic species, persistence and bioaccumulation. The regulatory action in Switzerland was intended to achieve the objectives of the North Sea Conference which aims to “phase out of those pesticides which are the most persistent, toxic and liable to bioaccumulate”. The PIC Circular does not include detailed information related to the stated concerns. However, based on the available information,⁷ the PMRA has identified the aspects of concerns as: bioaccumulation in fish, persistence in soil, effects on earthworms and toxicity to aquatic species.

Based on the available information from the European Commission and the Switzerland decisions, the aspects of concern that prompted the special review of quintozone are occupational and dietary exposure concerns, persistence in the environment, bioaccumulation in fish, effects on earthworms, and toxicity to aquatic organisms.

4.0 PMRA Evaluation of the Aspects of the Pest Control Product that Prompted the Special Review

Following the initiation of the special review, the PMRA requested information from provinces and other relevant federal government departments and agencies in accordance with subsection 18(2) of the *Pest Control Products Act*. No information related to the aspects of concern was received.

4.1 Occupational Exposure and Environmental Concerns (persistence, bioaccumulation in fish, effect on earthworms and toxicity to aquatic organisms)

The aspects of concern identified from the European Commission and the Switzerland decisions are related to the use of end use products. Due to the discontinuation of all end use products, the use of quintozone will not be permitted in Canada as of 26 April 2015. Exposure from any potential remaining use of quintozone (for bulb dip of ornamentals and transplant treatment of cole crops) up to 26 April 2015 is expected to be minimal and not of concern.

⁶ Rotterdam Convention, 2004. PIC Circular XX. December 2004.

⁷ Swiss Agency for the Environment, Forests and Landscape Substances, Soil and Biotechnology Division, 2004.

Two technical grade active ingredient products containing quintozone remain registered in Canada. Technical grade active ingredient products can be used only for the manufacturing or formulation of end-use products. The quintozone technical products are not currently used because of the discontinuation of end use products. Consequently, occupational and environmental exposure from these technical products is not expected.

Therefore, with the current registration status of quintozone, occupational exposure and risk, persistence in the environment, bioaccumulation in fish, and effects on aquatic organisms and earthworms are not expected to be of concern.

Should a registrant seek to register a new end use product containing quintozone in Canada, a health, environmental and value assessment will be conducted, including consideration of the above aspects of concern.

4.2 Dietary Exposure

Although the end use products are discontinued in Canada, Canadians may continue to be exposed to quintozone in imported foods from the use of quintozone in other countries. The PMRA has assessed dietary exposure from all food uses, including imported foods, and determined that dietary exposure is not of concern. With the discontinuation of all end use products in Canada, dietary exposure is further reduced and would not be of concern from imported commodities only.

A common mechanism of toxicity has not been identified for quintozone and other pesticide products. Therefore, a cumulative risk assessment is not required for quintozone.

5.0 Incident Report

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame.

As of 9 December 2014, the PMRA has received two minor human incident reports involving quintozone in 2007 and 2009. Both incidents were related to occupational handling of a product containing quintozone that is no longer registered for use in Canada. These incidents were classified as minor (eye/skin irritation).

6.0 Proposed Special Review Decision for Quintozone

Evaluation of available scientific information related to the aspects of concern, indicated that the registered products containing quintozone do not pose unacceptable risks to human health or the environment, taking into account current conditions of use. On this basis, PMRA under the authority of the *Pest Control Products Act*, is proposing to confirm the current registration of technical grade active ingredient products containing quintozone in Canada.

This proposed special review decision is a consultation document.⁸ The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information on the cover page of this document).

7.0 Next Steps

Before making a special review decision on quintozone, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a special review decision document, which will include the decision, the reasons for it, a summary of the comments received on the proposed decision and the PMRA's response to these comments.

⁸ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Appendix I Registered Products Containing Quintozene

Table 1 Registered Products Containing Quintozene as of 9 December 2014

Registration Number	Marketing Class	Registrant	Product Name
23334	Technical	Amvac Chemical Corporation	TECHNICAL GRADE QUINTOZENE
27212	Technical	Amvac Chemical Corporation	QUINTOZENE (TERRACLOR) TECHNICAL

Table 2 Discontinued Product Containing Quintozene as of 9 December 2014

Registration Number	Marketing Class	Registrant	Product Name
11425	Commercial	MGS Horticultural Inc.	QUINTOZENE 75% WETTABLE POWDER FUNGICIDE Last date of sale by registrant: 26 April 2011 Last date of sale by retail: 26 April 2012 Last date of use (Registration Expires): 26 April 2015

References**Published Information**

PMRA Document Number	Reference
1628699	Canada, 2009. Pest Management Regulatory Agency. Proposed Re-evaluation Decision PRVD2009-02, Quintozene.
1924804	Canada, 2010. Pest Management Regulatory Agency. Re-evaluation Decision RVD2010-06, Quintozene.
2405939	Canada, 2013. Pest Management Regulatory Agency Regulatory Note REV2013-06, Special Review Initiation of 23 Active Ingredients.
2440661	European Commission, 2000a. Commission Decision concerning the non-inclusion of quintozone in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant-protection products containing this active substance. (2000/816/EC).
2440662	European Commission, 2000b. Review report for the active substance quintozone.
2440663	Rotterdam Convention, 2004. PIC Circular XX. December 2004.

Unpublished Information

PMRA Document Number	Reference
2316063	Swiss Agency for the Environment, Forests and Landscape Substances, Soil and Biotechnology Division, 2004. Rotterdam Convention form for notification of final regulatory action to ban or severely restrict a chemical. 9 September 2004.